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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,011	08/05/2005	Andreas Boehm	P0777.70000US00	7235

23628 7590 09/14/2009

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EXAMINER	
DIXON, ANNETTE FREDRICKA	
ART UNIT	PAPER NUMBER
3771	

MAIL DATE	DELIVERY MODE
09/14/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/519,011	BOEHM ET AL.	
	Examiner	Art Unit	
	Annette F. Dixon	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 May 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is in response to the amendment filed on May 11, 2009. Examiner acknowledges claims 1-34 are pending in this application, with claim 1 having been currently amended.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. No amendment may introduce new matter into the disclosure of an application after its filing date. MPEP§ 608.04.

Specifically, claim 1 now recites the claim limitation “in the absence of any device to seal the nasal cavities from the throat and mouth"; however, the originally filed disclosure does not provide evidence that Applicant possessed the newly claimed invention at the time the invention was filed. In fact, the original specification of the instant invention discloses “seal[ing] the nasal cavities from the throat and mouth by means of the soft palate” (Page 5, Lines 21 and 22). As known in the art, the sealing of the nasal cavities from the throat and mouth by means of the soft palate is an event that

naturally occurs during swallowing and sneezing in order to prevent the entrance of nasal discharge into the mouth. Yet, by Applicant's claimed limitation, Applicant precluding and preventing the sealing of the nasal cavities by any means other than that which is naturally occurring and implies that no other means could be used to achieve the same effect. Applicant is reminded that "any negative limitation or exclusionary proviso must have basis in the original disclosure." MPEP §2173.05(i). There is no specific recitation or support for "the absence of any device to seal the nasal cavities from the throat and mouth" in the original disclosure as filed, despite Figure 6; therefore, the subject matter added to claim 1 is considered new matter and must be cancelled from the claims. Dependent claims 2-34 incorporate the subject matter from which they depend. See In re Johnson, 558 F.2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977); Ex parte Grasselli, 231 USPQ 393 (Bd. App. 1983), aff'd mem., 738 F.2d 453 (Fed. Cir. 1984); and Ex parte Parks, 30 USPQ2d 1234, 1236 (Bd. Pat. App. & Inter. 1993).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1, 3-6, 8-10, 13-16 and 18-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chantrel (EP0507707) in view of Djupesland (WO 00/51672).

As to Claims 1, 18, 29, and 30, Chantrel discloses a therapeutic aerosol device with a nebulizer device (2) with an aerosol generator (Column 4, Line 54 thru Column 5, Line 2) to which a gaseous medium for the generation of a main aerosol flow may be supplied from a supply device, and a pressure connection device (7) to supply pressure fluctuations which are superimposed on the aerosol main flow (51), and a nosepiece (2b) for supplying the aerosol into one of the two alae of the nose of a user connected to the nebulizer device (2). (Figure 1). Yet the Chantrel does not expressly disclose the use of a flow resistance device for use in the other of the two alae of the user's nose. However, at the time the invention was made the use of a flow resistance device was known. Specifically, Djupesland teaches the use of a flow resistance device in combination with a nose piece for the purpose of improving the deposition of aerosol particles in the nose and paranasal sinuses. (Page 19, Line 20 thru Page 20, Line 11). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Chantrel to include a flow resistance device, as taught by Djupesland for the purpose of providing a positive pressure environment in order to assist in the delivery of medicament during treatment.

As to Claim 3, the system of Chantrel and Djupesland teaches a nosepiece is embodied at one end for attachment to a connecting piece in the nebulizer device and at the other end for introduction into one nostril and the tight sealing of one of a user's nostril. Specifically, Djupesland teaches a nosepiece (30) for introduction into the nostril of a user and connected to a nebulizer (via medicament supply unit, 32). (Figure 3).

As to Claims 4 and 5, the system of Chantrel and Djupesland teaches the end of the nosepiece embodied for introduction into one nostril is embodied in the form of a truncated cone. Specifically, Djupesland teaches a truncated cone. (Figure 3).

As to Claims 6, 31, and 32, the system of Chantrel and Djupesland teaches a truncated cone shaped end of the nosepiece yet does not expressly disclose the connection angle. However, at the time the invention was made the angle of the truncated cone would be selected based upon the patient characteristics (neonate, child, adult, elderly) for the purpose of ensuring optimization of medicament in patient treatment. (Page 21, Lines 10-19). Moreover, Applicant has not asserted that the specific range recited provides a particular advantage, solves a stated problem or serves a purpose different from that of optimizing medicament delivery.

As to Claims 8 and 9, the system of Chantrel and Djupesland teaches a flow resistance device embodied for introduction into the other of the user's nostrils. Specifically, Djupesland teaches a flow resistance device (36).

As to Claim 10, the system of Chantrel and Djupesland teaches the flow resistance device includes a filter device. Specifically, Djupesland teaches a filter maybe utilized as a flow resistor (Page 15, Lines 13-14).

As to Claims 13-15, the system of Chantrel and Djupesland teaches the flow resistance device with a stopper in the form of a truncated cone. Specifically, Djupesland teaches a flow resistance device (36) and a truncated cone (40) with a first diameter on the top of the cone and a second diameter on the base of the cone. (Figure 3).

As to Claims 16, 19-21 and 33, the system of Chantrel and Djupesland teaches pressure fluctuations during the administration of treatment utilizing the aerosol device. Specifically, Chantrel teaches air is pulsed via air source (pump, 4); which provides a gas source to the nose piece (2b). (Figure 1).

As to Claim 22-24, the system of Chantrel and Djupesland teaches a sensor device for determining the aerosol flow or pressure fluctuations. Specifically, Djupesland teaches a sensor (43) coupled to a control unit (44) for controlling the flow rate of aerosol for the purpose of optimizing the particle deposition efficiency within the nasal airway. (Page 21, Line 1 thru Line 19).

As to Claim 25, the system of Chantrel and Djupesland teaches the use of multiple medicaments in the use of the nebulizing device. Specifically, Djupesland teaches the use of multiple medicaments including the administration of decongestants, anti-histamines, cromoglycates, steroids, and antibiotics. (Page 2, Lines 3-10).

As to Claim 26, 27 and 34, the system of Chantrel and Djupesland teaches the particle distribution size of the delivered medicament. Specifically, Djupesland teaches the particle distribution size within the range of about 1 to 10 micrometers. (Page 6, Lines 1-2).

As to Claim 28, the system of Chantrel and Djupesland teaches a handheld device. Specifically, Djupesland teaches the medicament supply unit (32) can be incorporated into a metered dose inhaler, which is a handheld device. (Page 18, Line 18-24).

6. Claim 2, 11, 12, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chantrel (EP0507707) in view of Djupesland (WO 00/51672) as applied to claim 1 above, and further in view of Brugger (DE3238149).

As to Claim 2, the system of Chantrel and Djupesland discloses a therapeutic aerosol device; yet does not expressly disclose the use of a suction channel. However, at the time the invention was made the use of a suction channel was known. Specifically, Brugger teaches the use of a suction channel in order to control the flow of the liquid droplets administered. (Page 3, Line 10 thru Page 4, Line 8). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system of Chantrel/Djupesland to include the suction channel, as taught by Brugger to enable control of the medicament administration to the patient.

As to Claims 11 and 12, the system of Chantrel and Djupesland discloses a therapeutic aerosol device; yet does not expressly disclose the connection of the flow resistance device to the nosepiece. However, at the time the invention was made the use of a connection element between the two elements placed within the nose were well known, as taught by Brugger (Figure 1) to enable close placement of the device for operational use. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system of Chantrel/Djupesland to include a connection piece between the elements, as taught by Brugger, to enable the device to be compact and connected.

As to Claim 17, the system of Chantrel and Djupesland discloses a therapeutic aerosol device; yet does not expressly disclose the use of a meandering airflow

channel. However, Brugger teaches the channel formation enables a smooth laminar transition from the airflow unit to the medicament to be delivered to the patient. As well known in the art, medicament is best administered to a patient in laminar flow rather than turbulent flow. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system of Chantrel/Djupesland to provide a means for transitioning the airflow profile of medicament delivered to the patient, as taught by Brugger for the purpose of ensuring optimal treatment.

7. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chantrel (EP0507707) in view of Djupesland (WO 00/51672) as applied to claim 1 above, and further in view of Landis et al. (5,687,715).

As to Claim 7, the system of Chantrel and Djupesland discloses a therapeutic aerosol device; yet does not expressly disclose the use of a balloon on the nose piece for the purpose of providing a seal to the patient's nose. However, at the time the invention was made the use of a balloon seal in a nasal interface was known. Specifically, Landis teaches a balloon (130) for insertion into the nares of a patient for the purpose of providing a sealing engagement and enabling patient comfort. (Figure 6 and Column 7, Line 55 thru Column 8, Line 18). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system of Chantrel/Djupesland to include a balloon seal, as taught by Landis for the purpose of providing patient comfort.

Response to Arguments

8. Applicant's arguments, filed May 11, 2009, with respect to the rejection of the claims under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement have been considered but are moot in view of the new ground(s) of rejection. As addressed in the new grounds of rejection, the limitation of "in the absence of any device to seal the nasal cavities from the throat and mouth" has been alleged by the Examiner to be a negative limitation as this limitation precludes and prevents the use of any other element in order to seal the nasal cavities from the throat and mouth, where this feature is not supported in the original disclosure as filed.

9. Applicant's arguments, filed May 11, 2009, with respect to the rejection of the claims under 35 U.S.C. 103(a) as being unpatentable over Chantrel (EP0507707) in view of Djupesland (WO 00/51672) have been fully considered but they are not persuasive. Applicant asserts the combination of the prior art made of record does not disclose or teach the claim limitation of "in the absence of any device to seal the nasal cavities from the throat and mouth"; thereby making the combination of the prior art references to be improper. Examiner respectfully disagrees with Applicant assertion. Though the device of Djupesland discloses two nosepieces and a mouthpiece, as the mouthpieces of Figures 3 and 4 lack connection to the associated nosepieces, there is nothing that would structurally preclude the embodiments of the nosepieces to be utilized without the mouthpiece utilized to close/seal the nasal cavities from the throat and mouth of the patient. Rather, as the mouthpiece is only used for the functional

purpose to close/seal the nasal cavities from the throat and mouth of the patient , this functionality could also be performed naturally and without the use of an additional element by the direction of the patient to swallow during administration of the medicament during use of the therapeutic aerosol device, as addressed in Knudson (6,636,767) (Column 3, Lines 7-10). Applicant is reminded, the omission of an element and retention of its function is an indicia of unobviousness. In re Edge, 359 F.2d 896, 149 USPQ 556 (CCPA 1966). Thus in light of the aforementioned reasoning the non-final rejection of the claims has been maintained.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Knudson (6,636,767) discloses “during swallowing, the soft palate SP flexes and extends, as shown in Figure 2, to close the nasapharynx NP thereby preventing fluid from the mouth M to the nasal passages N." (Column 3, Lines 7-10).

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette F. Dixon whose telephone number is (571) 272-3392. The examiner can normally be reached on Monday thru Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771

/Annette F Dixon/
Examiner, Art Unit 3771